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Tenecteplase (TNKase®) for Acute Ischemic Stroke

Pharmacy Education

Sun Hyee Park, PharmD, BCEMP
Manisa Tanprayoon, PharmD, BCPS
Pharmacy Department

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Medication Overview: Tenecteplase (TNKase)

Pharmacologic Category: Thrombolytic agent
Mechanism of Action:
Binds to fibrin, coverts plasminogen to plasmin → fibrinolysis
FDA-approved Indications:

- ST Elevation Myocardial Infarction (STEMI)
- Acute Ischemic Stroke (AIS) - Approved in March 2025

Note: Also use for Pulmonary Embolism (PE) (not FDA-approved)
Dosing:

- For STEMI and PE – <60 kg: 30 mg; ≥60 to <70 kg: 35 mg; ≥70 to <80 kg: 40 mg; ≥80 to <90 kg: 45 mg; ≥90 kg: 50 mg
- For AIS – 0.25 mg/kg (Max 25 mg/5 mL) IV bolus over 5 seconds
- No hepatic or renal dose adjustment required

Medication Safety

Warnings & Precautions

- Arrhythmias
- Bleeding (2-3%), including symptomatic intracranial hemorrhage (sICH)
- Cholesterol embolization
- Hypersensitivity reaction (including anaphylaxis and angioedema)
    - Reported frequency 0.4 to 5.1%
    - Risk can be 6x higher in patients taking ACE inhibitors

Adverse Reactions

- Heart failure (12%)
- Cardiogenic shock (6%)
- Antibody development (<1%)

Medication Safety

Contraindications:

- Acute or history of Intracranial Hemorrhage (ICH)
- Ischemic stroke ≤3 months
- Acute head trauma
- Intracranial/intraspinal surgery ≤3 months
- Subarachnoid Hemorrhage (SAH)
- GI malignancy/bleed ≤21 days
- Concomitant abciximab, IV aspirin
- Infective endocarditis
- Aortic arch dissection
- Intra-axial intracranial neoplasm

- Active bleeding diathesis, including but not limited to:
  - Platelet count <100,000/mm^3
  - Heparin ≤48 hours, resulting in abnormally elevated aPTT >40 secs
  - Enoxaparin treatment dose ≤24 hours
  - Concurrent use of warfarin with INR >1.7 or PT >15 secs
  - Concurrent use of direct thrombin inhibitors or direct factor Xa inhibitors
  - ≤48 hours (or longer if abnormal renal function)

Place in Therapy: Fibrinolysis for AIS

AHA/ASA 2019 Update to the 2018 Guidelines for the Early Management of AIS

3.6. Other IV Fibrinolytics and Sonothrombolysis	COR	LOE	New, Revised, or Unchanged
1. It may be reasonable to choose tenecteplase (single IV bolus of 0.25-mg/kg, maximum 25 mg) over IV alteplase in patients without contraindications for IV fibrinolysis who are also eligible to undergo mechanical thrombectomy.	IIb	B-R	New recommendation.

Drug	Alteplase	Tenecteplase
Dosing & Administration	0.09 mg/kg IV bolus over 1 min, followed by 0.81 mg/kg IV continuous infusion over 60 mins (maximum dose: 90 mg)	0.25 mg/kg (maximum dose: 25 mg) IV once over 5 secs
Fibrin Selectivity	+	+++
Resistance to PAI-1	+	++
Pharmacokinetics	t ½: <5 mins	Initial t ½: 20-24 mins, Terminal t ½: 90-130 mins

AHA = American Heart Association; AIS = acute ischemic stroke; ASA = American Stroke Association; PAI-1 = plasminogen activator inhibitor-1

Why Tenecteplase over Alteplase?

- Higher fibrin specificity = Targeted specificity and Reduced risk of bleeding complications
- Greater resistant to PAI-1 = Higher efficacy in clot lysis
- Longer serum half-life = Single bolus IV administration (tPA requires bolus and infusion doses)
- Non-inferior to Alteplase and potentially superior in patients who receive thrombectomy
- Easier to dose, prepare and administer = Reduce complications of care or potential medication errors. Potentially improve door-to-needle time.

PAI-1 = plasminogen activator inhibitor-1

Why Tenecteplase over Alteplase? *(Cont.)*

- Easier to dose – tPA has 2 different dosing for IV bolus and infusion
- Less time to prepare (Simple reconstitution) – tPA requires multiple steps
- No infusion, No pump: Single IV bolus over 5 seconds – tPA requires IV bolus then IV infusion given via smart pump
- 0.9% Normal Saline (NS)* flush instead of IV infusion of 0.9% NS
- More cost effective

*Not compatible with Dextrose

Updates Since Initial Implementation

- FDA approved TNKase® IV for the treatment of Acute Ischemic Stroke (AIS) in March 2025
- The 25-mg TNKase vial is commercially available and will replace the in-house TNK kit
- Refer to dosing table provided with the product
- Tenecteplase (TNKase®) an IV thrombolytic of choice for AIS
    - Alteplase (tPA) will remain on formulary for other indications (non-AIS) or when TNKase is not available (for AIS)

Order Entry – HealthBridge Order Set

Tenecteplase (TNKase) for Acute Ischemic Stroke can be order using the following:

- Ischemic Stroke Tenecteplase IV Administration Order Set OR
- Stroke Tenecteplase IV Administration Order Set

Dosing Instructions:

- Tenecteplase IV push 0.25 mg/kg actual body weight (Max dose 25 mg/5 mL) – Refer to dosing table (next slide)
- Ensure 0.9% Sodium Chloride Flush is ordered

The maximum recommended dose is 25 mg (5 mL)

Initiate treatment as soon as possible within 3 hours of symptom onset

Recommended dosage for AIS:

Patient weight (kg)	TNKase (mg)	Volume TNKase to be administered (mL)
<60 kg	15 mg	3 mL
≥60 to <70 kg	17.5 mg	3.5 mL
≥70 to <80 kg	20 mg	4 mL
≥80 to <90 kg	22.5 mg	4.5 mL
≥90 kg	25 mg	5 mL

Individualize dosing based on patient's weight per table above.

AIS Dose: 0.25 mg/kg ACTUAL body weight (Max dose 25 mg/5 mL)

Storage and Dispensing

Emergency Department ONLY:

- Main ER Pyxis and CT/MRI (Overridable)
- Store outside the refrigerator
- Restocked by pharmacy

All Other Patient Care Areas/Floors:

- Dose to be delivered by pharmacy
  - RN to call Pharmacy (x2854/x2856) in 15 minutes to confirm receipt of Tenecteplase order

In-house TNK kit will be replaced with the commercially available product (25-mg vial)

Preparation & Administration

https://www.tnkase.com/acute-ischemic-stroke/dosing-and-administration/reconstitution-administration.html

If using the 25-mg TNKase vial:

Step 1 Using a sterile syringe, aseptically **withdraw the Sterile Water for Injection** from the diluent vial. Only use the supplied Sterile Water for Injection diluent vial.

NOTE: If using the 50-mg TNKase vial, withdraw 10 mL of Sterile Water for Injection.

Step 2 **RECONSTITUTE** the 25-mg TNKase vial aseptically with 5.2 mL of Sterile Water for Injection by directing the stream into the lyophilized powder to obtain a final concentration of 5 mg/mL. Slight foaming upon reconstitution is not unusual; any large bubbles will dissipate if the product is allowed to stand undisturbed for several minutes.

NOTE: If using the 50-mg TNKase vial, aseptically reconstitute the 10-mL Sterile Water for Injection to obtain a final concentration of 5 mg/mL.

Step 3 **GENTLY SWIRL** until contents are completely dissolved. DO NOT SHAKE.
The reconstituted solution should be colorless or pale yellow and transparent. Because TNKase contains no antibacterial preservatives, reconstitute immediately before use. If the reconstituted TNKase is not used immediately, refrigerate the TNKase vial at 2°C to 8°C (36°F to 46°F) and use within 8 hours.

Step 4 **DETERMINE** the appropriate dose of TNKase (see table on previous page). WITHDRAW the required volume (in milliliters) from the reconstituted vial into a syringe. Discard any unused solution. **VISUALLY INSPECT** the reconstituted product in the syringe for particulate matter and discoloration prior to administration.

Step 5 Precipitation may occur when TNKase is administered in an intravenous line containing dextrose. **FLUSH** dextrose-containing lines with 0.9% Sodium Chloride Injection solution prior to and following single bolus administration of TNKase.

Step 6 **ADMINISTER** reconstituted TNKase as a single IV bolus over 5 seconds.

Step 7 **ASSESS AND MONITOR** patients according to each institution's protocol. Check for bleeding and signs of hypersensitivity. Monitor blood pressure. Perform neurological assessments. Consult the American Heart Association and American Stroke Association Guidelines for acute ischemic stroke for more information.

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Notable Changes with Tenecteplase (TNKase)

Emergency Department <u>ONLY</u>:

- **ED RN** or **ED Pharmacist** will prepare TNKase at bedside
- **Neurology Attending/Fellow/Resident** will administer TNKase

All Other Patient Care Areas/Floors:

- RN will acknowledge order of TNKase on HealthBridge
- **Main Pharmacy** will prepare TNKase
- Pharmacy technician will deliver TNKase to patient bedside
- **Neurology Attending/Fellow/Resident** will administer TNKase

****Do not prepare TNK until decision is made to give****

Spoiled product must be returned to pharmacy for replacement request

Stroke Alert Pharmacy Pathway

Overhead Notification:
Telecommunication overhead announcement
"Medical Alert Stroke Code" followed by location.
Pharmacy on standby for thrombolytic IV to be ordered

Non-HealthBridge Areas/Downtime	HealthBridge Areas
Paper Stroke Order Set in non-HealthBridge Areas **(MUST include pt. location, height, weight, and allergy info on order)**	Electronic order in HealthBridge (inpatient areas)
↓	↓
RN faxes the order to the Pharmacy's "STAT" fax machine (x2855) and calls to confirm receipt.	RN acknowledges the order In HealthBridge.
↓	↓
Pharmacy receives thrombolytic IV order & profiles order	Pharmacist reviews order (Enters appropriate total bolus dose, in Pharmacy notes) and verifies thrombolytic IV order
↓	↓
RN calls Pharmacy (x2856/x2854) in 15 minutes to confirm receipt of thrombolytic IV order.	

Thrombolytic IV Preparation & Dispensing

The admixing of thrombolytic IV will occur in the IV lab / Main Pharmacy.

Exception: Emergency Department – RN or ED Pharmacist will prepare IV thrombolytic

- Order for thrombolytic IV is verified/profiled
- IV lab receives a label for thrombolytic IV, prepares medication to provide the exact dose
- IV lab labels final product in syringe with patient-specific HealthBridge label
- Pharmacy sends technician to hand deliver thrombolytic IV to RN or MD for patient **for IMMEDIATE administration**

Refer to STK-03 Policy Attachment B

Patient Monitoring

** Same inclusion & exclusion criteria *and* post-medication administration monitoring as Alteplase (tPA)**

Patients treated with IV Thrombolytic: Assessment and Reassessment parameters

- Neuro checks are defined as NIH Stoke Scale Score (NIHSS) and Glasgow Coma Scale (GCS) not indicated.
- VS are assessed immediately prior to administration of IV Thrombolytic and reassessed:
  - Q 15 minutes x 2 hours
  - Q 30 minutes x 6 hours
  - Q 1-hour x 16 hours then Q 4 hours x 4 days
  - NIHSS q 4 hours for 24 hours post IV thrombolytic; after 24 hours, assess NIHSS q 4 hours for 4 days
  - Document VS in Flowsheets
  - Document NIHSS in Flowsheets

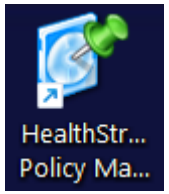
Refer to STK-04 Policy

Stroke Policies at Downstate

HealthStream Policy Manager

Stroke Center

- STK-01 Admission / Transfer of Acute Stroke Patients
- STK-02 Admission Transfer of Acute Ischemic Stroke Patients Receiving IV Thrombolytic
- STK-03 Medical Alert Stroke Code Neurology Stroke Program
- STK-04 Documentation Guidelines Acute Stroke Care
- STK-05 Transfer Admission and Initial Management of Patients with Acute Non-traumatic Intracerebral Hemorrhage



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